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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,775	08/18/2003	Oystein Lie	066849-019	4144
41552	7590	01/04/2006	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			WONG, JENNIFER SHIN SHIN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/643,775		LIE ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Jennifer Wong		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, 13-37, drawn to nucleic acids, classified in class 536, subclass 23.1.
  - II. Claims 11, 12, 38-62, drawn to methods to determine the origin of fish samples by assaying for nucleic acid variants, classified in class 435, subclass 6.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of invention I can be used in a materially different process such as for synthesizing nucleic acids or proteins as well as for diagnostic therapies.
3. Further, should Applicants elect inventions I and II, these groups are subject to an additional restriction requirement as follows.

Invention I reads on patentably distinct inventions drawn to multiple nucleic acid single nucleotide polymorphisms (SNPs), microsatellites, and pairs of primers. The claims encompass nucleic acid sequences set forth in Figures 1-9 and 11 consist of distinct nucleotide sequences, and a further restriction is applied to each invention. Applicants must elect a single variant and primer pair associated with said variant to be examined.

It is noted that each of the polymorphic variants and microsatellites constitutes distinct chemical compounds and each has a distinct functional property. The chemical structure of each polymorphism and of each molecule containing the polymorphism is distinct from each of the other polymorphisms. Similarly, chemical structure of each microsatellite and of each molecule containing the microsatellite is distinct from each of another microsatellite. SNPs are single base pair substitutions at one specific position within a nucleotide sequence whereas microsatellites are stretches of sequences usually less than 150 basepairs long that are repeated throughout the genome. Microsatellite sequences consist of 2-4 nucleotides repeats throughout its length, such as "CACACACACA..." repeated 50 times for a microsatellite of 100 basepairs. As SNPs and microsatellites are distinct chemical compounds and each as a distinct functional property, searches for SNPs, microsatellites are not co-extensive with one another. For example, a polymorphic polynucleotide comprising the sequence of SAL146A of figure 1-1 with an A at the underlined position is chemically, structurally and functionally distinct from a polymorphic polynucleotide comprising SAL78A of figure 1-1 with a C at the underlined position. Further, a search for a polynucleotide of SAL146A

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of figure 1-1 with an A at the underlined position would not be co-extensive with a search for a nucleic acid polynucleotide comprising SAL78A of figure 1-1 with a C at the underlined position. Additionally, a reference that renders obvious a polymorphic polynucleotide comprising the sequence of SAL146A of figure 1-1 with an A at the underlined position will not necessarily also render obvious polymorphic polynucleotide comprising SAL78A of figure 1-1 with a C at the underlined position. Similarly, a search indicating that polynucleotide of SAL146A of figure 1-1 with an A at the underlined position is novel or unobvious would not extend to a holding that polymorphic polynucleotide comprising SAL78A of figure 1-1 with a C at the underlined position is also novel and unobvious. Similarly, the microsatellite TN223 of figure 5-4 is chemically, structurally, and functionally distinct from another microsatellite such as TN369 of figure 5-4. Further, a search for TN223 of figure 5-4 would not be coextensive with a search for the TN369 of figure 5-4. Additionally, a search indicating that TN223 of figure 5-4 is obvious would not necessarily also render obvious TN369 of figure 5-4. Similarly, a search indicating that TN223 of figure 5-4 is novel and unobvious would not extend to a holding of TN369 of figure 5-4 is also novel or unobvious. Moreover, a search for a polymorphic polynucleotide comprising SAL78A of figure 1-1 with a C at the underlined position is chemically, structurally, and functionally distinct from a TN223 microsatellite of figure 5-4. For example, a search for polymorphic polynucleotide comprising SAL78A of figure 1-1 with a C at the underlined position would not be coextensive with the TN223 microsatellite of figure 5-4. Additionally, a reference which renders obvious polymorphic polynucleotide comprising

SAL78A of figure 1-1 with a C at the underlined position would not necessarily also render obvious TN223 of figure 5-4. Similarly, a reference that renders TN223 of figure 5-4 novel and unobvious would not extend to a holding that polymorphic polynucleotide comprising SAL78A of figure 1-1 with a C at the underlined position is also novel and unobvious.

Accordingly, the nucleic acids containing polymorphisms or microsatellites are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

Further, claims 2-5, 7-10, 14-17, 19-22, 24-27, 29-32, 34-37 reads on patentably distinct inventions drawn to multiple primer pairs. The claims encompass primer pairs set forth in Figures 1, 2, 4 and 11 can consist of distinct nucleic sequences, and further restriction is applied to each invention. Applicants must elect a single primer pair to be examined.

It is noted that each of the nucleic acid sequences constitute distinct chemical compounds and each has a distinct functional property. The chemical structure of each nucleic acid sequence and of each molecule of a nucleic acid sequence is distinct from each of the other nucleic acid sequence. For example, a primer pair comprising AGTTATTGCGGCTTCCTGTG and AAACAAAACATGGGGGAGAAA (GM183) of figure 11-80 is chemically, structurally and functionally distinct from a primer pair comprising

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TGCACTTTGGGGGATG and TAATAGCTCTGCCGTTTGTTTC (GM285) of figure 11-88.

Further, a search for a primer pair comprising AGTTATTGCGGCTTCCTGTG and AAACAAAACATGGGGGAGAAA (GM183) of figure 11-80 would not be co-extensive with a search for a nucleic acid comprising TGCACTTTGGGGGATG and

TAATAGCTCTGCCGTTTGTTTC (GM285) of figure 11-88. Additionally, a reference which renders obvious AGTTATTGCGGCTTCCTGTG and

AAACAAAACATGGGGGAGAAA (GM183) of figure 11-80 will not necessarily also render obvious TGCACTTTGGGGGATG and TAATAGCTCTGCCGTTTGTTTC (GM285) of figure 11-88. Similarly, a search indicating that AGTTATTGCGGCTTCCTGTG and AAACAAAACATGGGGGAGAAA (GM183) of figure 11-80 is novel or unobvious would not extend to a holding TGCACTTTGGGGGATG and TAATAGCTCTGCCGTTTGTTTC (GM285) of figure 11-88 is also novel or unobvious. Accordingly, a search of more than one of the primer pairs presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. Accordingly, Applicants are required to elect one (1) set of primer primers selected set forth in Figures 1, 2, 4, or 11. Note that this is not a species election.

In summary, should Applicants elect invention I, Applicants should elect a variant and the primers which are associated with the variant.

4. Further, should Applicants elect invention II, this group is subject to an additional restriction requirement as follows.

Invention II reads on patentably distinct inventions drawn to methods of detecting nucleic acid sequences using multiple nucleic acid primer pairs. The claims encompass polymorphic variants and microsatellites and their respective primer pairs of the nucleic acids of figure 1-9 and 11. The polymorphisms, microsatellites, and primer pairs set forth in figures 1-9 and 11 consist of distinct nucleotide sequences, and a further restriction is applied to each invention. Applicants must elect a single polymorphic nucleic acid sequence and the pair of primers of said sequence to be examined.

It is noted that each nucleic acid sequences constitutes distinct chemical compounds and each has a distinct functional property. The chemical structure of each nucleic acid primer pairs and of each molecule containing the nucleic acid sequence is distinct from each of the other nucleic acid sequences. For example, a polynucleotide comprising the microsatellite GM285 and its respective primers in Figure 11-88 is chemically, structurally and functionally distinct from a polynucleotide comprising the polymorphic SNP107 and its respective primers of Figure 4-1. Further, a search for a nucleic acid comprising the microsatellite GM285 and its respective primers in Figure 11-88 would not be co-extensive with a search for a nucleic acid comprising the polymorphic SNP107 and its respective primers of Figure 4-1. Additionally, a reference which renders obvious a polymorphic or microsatellite nucleic acid sequence and its primer pair for will not necessarily also render obvious a different polymorphic or microsatellite nucleic acid sequence and its primer pair. Similarly, a search indicating that a particular polymorphic or microsatellite nucleic acid sequence and its primer pair



is novel or unobvious would not extend to a holding that another polymorphic or microsatellite nucleic acid sequence and its primer pair is also unobvious.

Accordingly, each nucleic acid sequence and its primer pair are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

Absent evidence to the contrary, each such nucleotide sequence and its primer pair is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

5. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I and II require different searches that are not coextensive. For instance, the nucleic acids of invention I is not co-extensive with a patent and non-patent literature search of the methods of determining the origin of fish samples of invention II. Further a finding that nucleic acids of invention I is anticipated or obvious over the prior art would not necessarily extend to a finding that the methods of invention II were also anticipated over the prior art. Similarly, a finding that nucleic acids of invention I is novel and unobvious over the prior art would not extend to a finding that the methods of invention II are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1).

However, this application fails to comply with the requirements of 37 CFR 1.821-25 because of the lack of sequence identifiers (SEQ ID Nos.) have not been containing each of the disclosed sequences has not been filed. See, for example, the entire specification and Figures 1-9 and 11. In response to this Office action, Applicants must comply with the requirements of 37 CFR 1.821-1.825. In particular, **Applicant is required to submit an amendment directing inserting SEQ ID Nos. into the appropriate pages in the specification and figures.**

7. A telephone call was made to Cathryn Cambell on December 20, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Wong whose telephone number is (571) 272-1120. The examiner can normally be reached on Monday-Friday; 8 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Wong

  
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12/28/05